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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,178	04/26/2006	Christina Mertens	1-2003.020 US	3452

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Intervet/Schering-Plough Animal Health
Patent Dept. K-6-1, 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

EXAMINER	
BAEK, BONG-SOOK	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
08/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/577,178	MERTENS ET AL.	
	Examiner	Art Unit	
	BONG-SOOK BAEK	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

The amendment filed on June 1, 2009 is acknowledged. Claims 1, 3-5, 7-8, 11-12, 14, 16, and 20 have been amended. Claims 1-20 are under examination in the instant office action.

Applicants' arguments, filed on June 1, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Responses are limited to Applicants' arguments relevant to either reiterated or newly applied rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 11-12, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,189,053 (Issue Date: 2/23/1993).

US Patent 5,189,053 teaches the compounds of formula (I) as recited in the instant claim 1 (column 1, line 5-column 2, line 68 and claim 1) and the elected species, 5-chloro-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-(4,5-dicyano-1H-imidazol-2-yl)-3-methyl-1H-pyrazole composition (column 21, lines 41-43, compound 22c), and a method of using the compounds for

combating insects, acarids or animal endoparasites including ticks (claims 14-17 and column 3, lines 4-19). It further teaches the compounds are active systemically, especially against animal ecto- and endoparasites (column 3, lines 31-33) and compositions containing the compounds can be in the form of a preparation for oral (systemically applied), parenteral or dermal application, e.g. in the form of powders, solutions, suspensions, tablets, capsules, drenches, boluses, pour-ons-, dips, sprays, injectables or as food additives (column 4, lines lines 27-41). In addition, the reference further discloses that 100mg/kg of compound 22c (elected species) is orally administered (considered as "systemically administered") to mice for parasitic infection *in vivo* test (column 29, lines 59-column 30-line 2). Furthermore, it teaches that the invention provides a method of combating pests such as insects and acarids at a locus or host for the pest, infested or liable to be infested therewith (column 3, lines 34-39), wherein a host liable to be infested is an uninfested animal. Thus, the reference encompasses the instant claim 22 as amended.

As such, the instant claims are anticipated by US Patent 5,189,053.

Response to Applicant's arguments

Applicants argued that Willis never considers the deterring effect of the compounds of Formula I before infestation occurs and for instance, Willis does not measure the number of alive, unattached, and unengorged ticks and, therefore, does not describe "deterring ticks from infesting the animal."

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., deterring effect of the compounds of Formula I before infestation and measuring the number of alive, unattached, and unengorged ticks) are not recited in the rejected claim(s). Although the claims

are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Also, the specification does not define the term "deterring", thus when a broadest reasonable interpretation is given, "deterring" encompasses preventing or inhibiting according to the definition of Merriam-Webster online dictionary. Therefore, combating or killing ticks as taught by US Patent 5,189,053 reads on "deterring".

In the alternative, since the reference teaches the use of the same compound for combating ticks in the animal infested or liable to be infested therewith, the deterring effect as Applicants argued necessarily occurs. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. MPEP §2112. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d

1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 and 13-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over US Patent 5,189,053.

As stated above in 102 rejection, US patent 5,189,053 teaches all the limitations of claims 1-5.

The reference differs from the instant claims 6-10 and 13-19 insofar as it does not specifically teaches that the animal is a dog or a cat and that the compound is applied in an initial

dose of 4 mg/kg bodyweight of the animal, followed by weekly administration of doses of 2mg/kg bodyweight of the animal.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to apply the haloarylpyrazole compound including the elected species as taught by US patent 5,189,053 to any animals including dogs or cats with a reasonable expectation of success of getting the same effect since US patent 5,189,053 teaches the haloarylpyrazole compound is useful for controlling animal ecto- and endoparasites such as ticks.

With regard to the initial dose and weekly administration dose, it would have been prima facie obvious to one of ordinary skill in the art at the time of invention was made to optimize dosage of the compound for each animal and based on the severity of infestation. As anyone of ordinary skill in the art would appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude; for instance, an extremely heavy patient or one having an unusually severe infestation would require a correspondingly higher dosage. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity. The specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition and age of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating

such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.)

Response to Applicant's arguments

In response to the argument regarding "deterring ticks from infesting an animal", the same response as stated above is applied.

In response to the argument that Willis and the level of ordinary skill do not teach or suggest the element of "wherein the animal is a dog or cat" and Willis does not even mention administering the compound of formula I to any animal but mice, a reference is not limited to its working examples, but must be evaluated for what it teaches those of ordinary skill in the art. *In re Boe, 355 F.2d 961, 148 USPQ 507 (C.C.P.A 1966). In re Chapman, 357 F.2d 418, 148 USPQ 711 (C.C.P.A. 1966).* Although Willis does not show a specific working example of administering the compound of formula I to dog or cat, it teaches that the compound of formula I is active systemically against animal ecto- and endoparasites such as ticks, thus one of ordinary skill in the art would have been motivated to administer the compound of formula I to any

animals including dogs or cats. One having ordinary skill in the art would have expected that a compound, which is active against ticks in mice, would also effective for the same purpose in dogs or cats. US 2003/0199579 is cited as only evidentiary reference to show that a compound effective for controlling tick is universally used for any animals including as dog and cat as well as mice. US 2003/0199579 teaches a compound effective for controlling fleas and ticks, which is used for domestic animals, pets such as dog and cat as well as for rodential animals such as mouse and rat (abstract and [0024]).

In response to the arguments that Claims 7, 8, 14, and 16 are not obvious because Willis does not teach or suggest an initial dosage of 4 mg/kg bodyweight of the animal followed by weekly administration of doses of 2 mg/kg bodyweight of the animal, it would have been prima facie obvious to one of ordinary skill in the art at the time of invention was made to optimize dosage of the compound for each animal and based on the severity and type of infestation as stated in the previous action mailed on 1/7/2009. As applicants stated, a dosage of 100 mg/kg is administered to mice for killing animal endoparasite in the example disclosed in Willis, however the dosage serves as useful guideposts for the physician to estimate what dose of the claimed compound has been given to animal and whether there is no toxicity when administered to the animal. There are many reasons for varying dosages, including by orders of magnitude; for instance, an extremely heavy patient or one having an unusually severe infestation would require a correspondingly higher dosage. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity. In addition, it is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ 33; *In re Russell*, 169 USPQ 426. "[W]here the general

conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.") In the instant case, the dosage of active ingredient is clearly a result-effective variable. It would have been customary for an artisan of ordinary skill in the art to determine the optimal dosage of the claimed compound in order to best achieve the desired results.

In response to the argument that it was applicant who determined that the claimed compound may be used to deter ticks from infesting the animal and the office is using improper hindsight to arrive at the invention encompassed by claim 1, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In addition, the reference already teaches that the claimed compound can be used for animal hosts infested or liable to be infested with a pest such as tick as stated above. Applicants asserted unexpected results but has not exhibited said unexpected results in a side by side comparison with the closet prior art disclosed supra.

Provisional Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-18 of copending Application No. 11/698683. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '683 application are also drawn to a method for controlling a parasitic insect and/or acarid infestation comprising administering the same arylpyrazole compounds with the same core structure and substitution including the elected species, 5-chloro-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-(4,5-dicyano-1H-imidazol-2-yl)-3-methyl-1H-pyrazole, wherein the term "parasitic insect and acarid" encompass ectoparasites, which include the egg, larval, pupal, nymphal, and adult stages of lice, fleas, mosquitoes, mites, ticks biting, or nuisance fly species in light of specification of '683 application (p10, [63]). Although the instant claims do not recite a nitroamine which is recited in the '683 claims, the instant claims recite the open language "comprising", which does not exclude additional unrecited elements (see MPEP 2111.03).

This is a provisional obviousness-type double patenting rejection.

Applicant's request that the Double Patenting rejection be held in abeyance until it is made permanent is noted but will be maintained in this Office Action and future Office Actions until withdrawn.

Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-11 and 19-20 of copending Application No. 10/577232. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '232 application are also drawn to a method for

controlling the infestation of an ectoparasite including ticks comprising administering the same arylpyrazole compounds with the same core structure and substitution including the elected species, 5-chloro-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-(4,5-dicyano-1H-imidazol-2-yl)-3-methyl-1H-pyrazole. Although the instant claims do not recite one or more spinosyns which are recited in the '232 claims, the instant claims recite the open language "comprising", which does not exclude additional unrecited elements (see MPEP 2111.03).

This is a provisional obviousness-type double patenting rejection.

Applicant's request that the Double Patenting rejection be held in abeyance until it is made permanent is noted but will be maintained in this Office Action and future Office Actions until withdrawn.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 9:00-6:00 Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian-Yong S Kwon/
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